

*Article***THE BIOLOGICAL DEPOSIT REQUIREMENT:  
A Means Of Assuring Adequate Disclosure***David J. Weitz* †**Table of Contents**

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**I. INTRODUCTION**

The future of the United States as an economic and technological leader lies in its ability to innovate. The patent system has long played an integral role in motivating innovation.<sup>1</sup> The Founders foresaw the force with which creativity and invention would shape our country's future<sup>2</sup> and incorporated the Patent Clause<sup>3</sup> into the Constitution to insure that it provided for the evolution of technology in America.<sup>4</sup> There is little doubt that the Patent system has played an instrumental role in the development of industry and innovation in this country.<sup>5</sup>

Full and enabling disclosure of an invention is the motivation and consideration for which the government grants a patent monopoly to an inventor. It is this disclosure that enables the public to freely practice the invention after the patent term expires. The Supreme Court has described the public disclosure and use of the invention as the "centerpiece of federal patent policy."<sup>6</sup> The monopoly that is granted to the inventor is secondary and incidental to the public's interest in disclosure.<sup>7</sup> Early disclosure of an invention is desirable because it "provides a basis for further advances in the technology involved"<sup>8</sup> and fortifies "scientific norms [by] promoting publication of research results in replicable form."<sup>9</sup>

Congress, through its enactment of 35 U.S.C. § 112, declared that an inventor must provide a "full, clear, concise and exact" description of the invention so as to "enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."<sup>10</sup> If the

inventor fails to comply with this disclosure standard, a patent monopoly for the invention is denied.

The world's next industrial revolution will be in the area of biotechnology. Some anticipate that the U.S. biotechnology market will increase sixteen percent per year over the next ten years, reaching annual sales of \$14.5 billion by the year 2002.<sup>11</sup> In light of the faltering U.S. economy and the prospect of truly miraculous biotechnological innovations on the horizon, this is not the time for the United States to stifle the development of biotechnology in America by undermining the exchange of information within the industry. Unfortunately, the disclosure standard announced by the Federal Circuit in *Amgen, Inc. v Chugai Pharmaceutical Co.*<sup>12</sup> threatens to do so.<sup>13</sup>

In 1991, the Federal Circuit, in a case of first impression, considered whether a biological deposit<sup>14</sup> is necessary to satisfy the best mode requirement for patents involving "novel genetically-engineered biological subject-matter."<sup>15</sup> Rather than adopting a rule requiring that a biological deposit be made in order to satisfy the enablement element of the best mode requirement, the court ruled that a biological deposit is not required if the biological material necessary for practicing the invention "can be prepared without undue experimentation from known materials, based on the description in the patent specification."<sup>16</sup> This is the first judicial interpretation of the recently enacted Patent and Trademark Office (PTO) guidelines concerning the "Deposit of Biological Materials" for patent purposes.<sup>17</sup> The PTO guidelines outline the procedures and conditions for depositing biological material,<sup>18</sup> when a deposit is necessary to satisfy the disclosure requirements of 35 U.S.C. § 112.<sup>19</sup> The guidelines do not address "the substantive issue of whether a deposit is required under any particular set of facts."<sup>20</sup> Rather, the situations in which a deposit is required was left to judicial interpretation.<sup>21</sup> As will be discussed below, the Federal Circuit's holding in *Amgen* is simply a restatement of the enablement requirement as it has been applied to other technologies.<sup>22</sup> The issue raised here is whether the nature of biotechnology as a technology and an industry necessitates the legislative enactment of a specialized disclosure standard.

The rule the Federal Circuit adopted as to whether a biological deposit is required in order to satisfy the best mode disclosure requirement of § 112 has drawn some sharp criticism. The Taxpayer Assets Project, an organization focusing on the nature and fairness of the bargain the government makes when transferring public assets to the private sector, has taken the position that the Federal Circuit's interpretation of the disclosure requirement "sacrifices the public interest, because it allows an inventor to conceal the invention's secrets . . . and threatens to fatally deprive our patent system of its public value."<sup>23</sup> This group is not alone. In conjunction with Genetics Institute's writ for certiorari in *Amgen*, several other interest groups submitted amicus briefs expressing their concerns over the Federal Circuit's interpretation. They contend that the court's holding undermines the patent disclosure requirements and will ultimately thwart the flow of information in the biotechnology industry.<sup>24</sup>

This Article considers whether legislation creating a best mode deposit requirement is socially desirable as a means of motivating innovation. By reviewing the evolution of the enablement requirement as it has been applied to biotechnology, this note highlights the shortcomings of the present enablement standard as a means of assuring that the public receives the disclosure for which it bargained. This note then considers the effect a deposit requirement would have on the patent system's goal of motivating innovation. In light of the above discussion, this note proposes a rule requiring the deposit of materials used in the best mode embodiment as both a necessary and desirable means of furthering the patent system's goals of motivating disclosure and innovation.

## II. BIOTECHNOLOGY AND THE ROLE OF BIOLOGICAL DEPOSITS IN THE INNOVATIVE PROCESS

Biotechnology has been defined as "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses."<sup>25</sup> This simply means that biotechnology covers the use of biological material as machinery in a process.<sup>26</sup> Biotechnology differs from most fields in that the "machinery" used, living matter, cannot always be reproduced from a written description, no matter how comprehensive.<sup>27</sup> There are circumstances where "life simply cannot be reduced to a written recipe."<sup>28</sup>

The biological deposit system serves to remedy the fact that newly isolated or created biological materials cannot always be reproduced from a written description. The scientific community has taken the approach of requiring researchers, as a condition of publishing their scientific results, to deposit any cell lines used in their research that are not already on deposit.<sup>29</sup> The government has also taken the position of requiring the deposit of organisms developed through the use of government funding. Any party receiving funds from the National Institutes of Health (NIH) or another Public Health Service (PHS) division must deposit all "unique or novel biological materials and resources developed with PHS funds."<sup>30</sup> In contrast, an inventor need not make biological deposits in order to get a government sanctioned monopoly, i.e., a patent. Biological depositories are the means by which scientists make biological material publicly available by functioning as clearinghouses for reference samples of biological materials.<sup>31</sup> Depositories may be public or private, for-profit or non-profit. In general, depositories receive samples from scientists, give the samples identification numbers and then store the samples under conditions that preserve their viability over an extended period of time.<sup>32</sup> The cost of

making a biological deposit is presently about \$1000.<sup>33</sup> As part of the deposit agreement, scientists agree, for a specified period of time, to replace samples on deposit that are lost or die. Samples of the deposited material are then available upon request to members of the scientific community.<sup>34</sup>

The American Type Culture Collection (ATCC) is perhaps the best known depository in the world. The ATCC was organized in 1925 as a non-profit organization for the purpose of collecting and distributing biological materials. The ATCC presently has 50,000 strains of organisms on deposit; 10,000 in the Patent Depository.<sup>35</sup> The ATCC was the first depository to receive a deposit from an inventor as a means of satisfying the patent disclosure requirements. On July 8, 1949, Parke Davis Co. deposited a culture of *Streptomyces venezulae* in conjunction with a patent application for a process for the manufacture of chloramphenicol.<sup>36</sup> The ATCC was recognized as a depository for patent purposes in a 1952 letter from the PTO. In 1981, the ATCC became the first depository to acquire the status of International Depository Authority under the Budapest Treaty enacted by the World Intellectual Property Organization (WIPO).<sup>37</sup>

### III. THE PRESENT DISCLOSURE REQUIREMENTS FOR BIOTECHNOLOGICAL INVENTIONS

Neither the courts nor the PTO have adopted the scientific community's policy of absolutely requiring the deposit of biological samples.<sup>38</sup> Rather, the courts view biological deposits as a method of complying with the enablement requirement rather than as a rule of law.<sup>39</sup> The PTO guidelines predicate whether a deposit is required on whether the biological material necessary for practicing the invention is "known and readily available to the public or can be made or isolated without undue experimentation."<sup>40</sup> This is merely a restatement of the enablement requirement.<sup>41</sup>

The enablement requirement of the patent code is designed to guarantee that the inventor delivers her end of the bargain. A patent is frequently analogized to a contract where the patentee is obligated to place the invention in the public domain as consideration for the right to exclude others from making, using or selling the invention.<sup>42</sup> Section 112 paragraph 1 of the patent code contains two disclosure requirements that must be satisfied before an inventor may receive a patent monopoly: the enablement requirement and the best mode requirement.

The enablement requirement is the quid pro quo of the monopoly grant. An enabling disclosure "is necessary in order to give the public, after the privilege shall expire, the advantage for which the privilege is allowed, and is the foundation for the power to issue the patent."<sup>43</sup> Disclosure must enable one of ordinary skill in the art to practice the invention without undue experimentation. In the area of biotechnology, however, it is recognized that even a "production specification" may not be enabling if the biological material necessary for practicing the invention is not readily available to the public.<sup>44</sup> In such cases, the deposit of the biological material is necessary to place the invention in the public domain.<sup>45</sup>

The best-mode requirement provides that "the specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention."<sup>46</sup> The best-mode requirement was first formally introduced into the patent code in the Patent Act of 1870.<sup>47</sup> Surprisingly, the best-mode requirement lay dormant<sup>48</sup> until 1965, when the Seventh Circuit invalidated a patent because it failed to disclose the best-mode.<sup>49</sup> Since then, the best-mode requirement has become a recurrent issue in assessing patent validity. "The purpose of the best mode requirement is to ensure that the public, in exchange for the rights given the inventor under the patent laws, obtains from the inventor a full disclosure of the preferred embodiment of the invention."<sup>50</sup>

The best-mode requirement is often of great significance to the public since, in many instances, the best mode is the most economically viable method of practicing the invention. This is especially true in process patents, where the best mode is likely to be determined by economic efficiency.<sup>51</sup> Biotechnology inventions often involve the development of new biological material used as the machinery to produce a product. In such instances, the public's interest in the best mode disclosure centers on obtaining access to the process machinery, the particular strain or variant that the inventor subjectively believes is the best.<sup>52</sup> This is often the strain that is the most economically practical for mass production of the biologically active product.<sup>53</sup>

The Federal Circuit has provided a two-step analysis for compliance with the best-mode requirement.<sup>54</sup> First, a court must determine "whether, at the time the inventor filed his patent application, he knew of a mode of practicing his claimed invention that he considered to be better than any other."<sup>55</sup> This is a subjective inquiry into the inventor's state of mind<sup>56</sup> and presents a question of fact.<sup>57</sup> The court must then determine whether the inventor 'concealed' his preferred mode from the 'public'.<sup>58</sup> Concealment addresses whether the inventor provided a disclosure that is sufficient to enable one of ordinary skill in the art to practice the best mode.<sup>59</sup>

The question answered by the Federal Circuit in *Amgen*, whether a biological deposit is necessary to satisfy "the best mode requirement for patents involving novel genetically-engineered biological subject matter,"<sup>60</sup> addressed the enablement of the

specification with regard to the best mode.<sup>61</sup> The Federal Circuit found that when "the organism is created by the insertion of genetic material into a cell obtained from generally available sources, then all that is required is a description of the best mode and an adequate means of carrying out the invention. . . ." <sup>62</sup> "If the cells can be prepared without undue experimentation from known materials, based on the description in the patent specification, a deposit is not required."<sup>63</sup> "What is required is an adequate disclosure of the best mode, not a guarantee that every aspect of the specification be precisely and universally reproducible."<sup>64</sup>

The *Amgen* holding essentially reiterates 37 C.F.R. § 1.802(b);<sup>65</sup> a guideline designed to outline what should be done if a deposit is required.<sup>66</sup> In order to understand the significance of the court's holding, it is necessary to analyze what the court considers an "adequate disclosure," and what it considers biological material that "can be made or isolated without undue experimentation."<sup>67</sup>

## A. Adequate Disclosure

The purpose behind the first paragraph of § 112 is to ensure that the patent applicant provides an *adequate disclosure* of the invention for which patent protection is sought.<sup>68</sup> This includes an enabling disclosure of both the invention and the best mode of carrying out that invention.<sup>69</sup> The adequacy of a patent's disclosure has two components. One is particularity: whether the specification provides a person of ordinary skill in the art with all of the tools necessary to practice the invention. Adequacy also addresses reproducibility, the level of precision the specification must enable under the patent laws.

Courts tend to curb the particularity element of the adequate disclosure standard in the interest of specification brevity. "Not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be. United States specifications have often been criticized as too cluttered with details to give an easy understanding of what the invention really is."<sup>70</sup> Requiring biological deposits does not raise this concern. As a method for complying with the § 112 disclosure requirements, biological deposits do not present a problem of loquacity. Rather, a biological deposit is the most condensed means available for placing an invention in the public domain.

The reproducibility aspect of the "adequate disclosure" standard addresses how closely a person of ordinary skill in the art should be able to recreate an invention from the specification without engaging in undue experimentation. Reproducibility is an important issue when evaluating a specification's compliance with the best mode requirement. The best mode requirement requires the inventor to enable the embodiment of the invention that distinguishes it as the best mode in the mind of the inventor. Whether a biological deposit is required to provide the level of reproducibility required by the best mode requirement was the issue addressed in *Amgen*. The court ruled that the specification need not enable exact duplication. Rather, the ability to repeat the experiment and achieve *similar* results is sufficient.<sup>71</sup> In support of this ruling, the Federal Circuit relied on *In re Gay*,<sup>72</sup> a 1962 Court of Customs and Patent Appeals decision, as support for this interpretation of what constitutes adequate disclosure in biotechnology cases.

*Gay* involved a patent application claiming containers used in steam rice cookers.<sup>73</sup> These containers hold a premeasured amount of rice and have numerous minute openings large enough to allow steam and water to escape while retaining the rice grains.<sup>74</sup> The Patent Office Board of Appeals rejected the application because, in part, the specification did not provide an enabling disclosure of the best mode.<sup>75</sup> The Court of Customs and Patent Appeals reversed, finding that the specification adequately described the materials to be used and their essential characteristics.<sup>76</sup> While the specification failed to point out the exact number or positioning of the perforations or their exact size, neither the "perforation size, positioning or number" was particularly important to the functioning of the invention.<sup>77</sup> The best mode, one in which the container was designed to resist tears, was adequately reproducible from the specification because a staggered perforation design was both known in the art and depicted in an accompanying drawing.<sup>78</sup> Based on this, the *Gay* court concluded that "one skilled in the art 'could produce the article with a minimum amount of experimentation' if any experimentation at all be necessary."<sup>79</sup>

Under *Gay*, "adequate disclosure" does not guarantee "that every aspect of the specification be precisely and universally reproducible."<sup>80</sup> *Gay* requires the enablement of functionally equivalent although not necessarily identical embodiments of an inventor's best mode. Merely requiring the best mode disclosure to enable a functionally equivalent, non-identical embodiment does not deprive the public access to its bargained-for disclosure as long as all the attributes of the embodiment that make it the best mode are reproducible. Under the facts of *Gay*, one of ordinary skill in the art was able to create a device that had all the essential functional attributes possessed by the inventor's best mode.

The adequate disclosure standard under *Amgen* does not guarantee public access to an embodiment that is functionally equivalent to the inventor's best mode embodiment. In finding that the best mode was adequately enabled in *Amgen*, the court relied on Genetics Institute's expert's testimony that "with the vectors and the sequences shown in Example 10, I have no doubt that someone eventually could reproduce -well, could generate cell lines [sic, strains] making some level of EPO, and *they could be better, they could be worse*

in terms of EPO production."<sup>81</sup> By not employing a deposit requirement as a reproducibility guarantee, the court expressed a willingness to grant and hold valid patents that in fact fail to enable embodiment that is functionally equivalent to the inventor's best mode. The adequate disclosure standard set forth in *Gay* does not instruct courts to uphold patents that provide only a probability that the public will have access to the best mode embodiment. Furthermore, as a policy rationale, the public should not be left with only a probability that the best mode is enabled when better methods of insuring adequate disclosure of inventions are available. Biological deposits can be used to guarantee the actual disclosure of the best mode embodiment and should be required absent strong policy interests balancing against their use.<sup>82</sup>

The problem with the *Amgen's* adequate disclosure analysis is that it fails to adapt the adequate disclosure standard to the technology involved. *Amgen* involved the genetic expression of a hormonal protein in mammalian cells. In order to practice the best mode from the patent specification, a person of ordinary skill in the art has to perform several genetic transformations. These transformations are not necessarily reproducible.<sup>83</sup> After *Amgen*, it is unclear how many genetic transformations can be performed on a cell line before that cell line is no longer considered a "starting material." The Federal Circuit did not require the genetically engineered Chinese hamster ovary cells to be "known or publicly available." The Federal Circuit did not even require the terminal genetic transformation to be performed on a *generally available cell line*. Rather, the court only required "a cell obtained from generally available sources."<sup>84</sup> This is a much looser "known or publicly available starting material" standard since it allows the inventor to perform multiple genetic transformations on a publicly available organism without depositing the product. As the number of intermediate genetic transformations increase, the likelihood of reproducing an embodiment (genetically engineered organism) that is functionally equivalent decreases.

Requiring biological deposits as a means of insuring a higher level of reproducibility than the court presently requires would not be inconsistent with the holding in *Gay*. The court in *Gay* noted that more weight should have been given to the drawings that accompanied the specification when the PTO considered whether § 112 had been satisfied.<sup>85</sup> Biological deposits serve the same function as the drawings in *Gay*.<sup>86</sup> Deposits give the public the most complete depiction of the invention possible. It is ironic that the Federal Circuit used *Gay* to justify limiting the use of this form of disclosure.

## **B. Undue Experimentation**

Undue experimentation is the other element of the disclosure standard that was elucidated by the *Amgen* decision and is closely related to the adequate disclosure standard. Adequate disclosure describes how much guidance for reproducing an invention a patent applicant must provide. By contrast, the "undue experimentation" standard requires that the patent's teachings enable one of ordinary skill to practice the invention without the need to exercise more than routine skill. That is, undue experimentation is required if one must reinvent the invention in order to practice the invention. A specification is not enabled if "undue experimentation" by one of ordinary skill in the art is needed to practice the invention. The "undue experimentation standard is violated when the amount of time, effort or inventiveness needed to reproduce the invention from the specification is too large to justify a patent grant."<sup>87</sup> Undue experimentation was recognized as a standard for what constitutes an adequate disclosure under § 112 long before the enactment of the 1952 Patent Act.<sup>88</sup> No bright line rule regarding what constitutes undue experimentation has ever been articulated.<sup>89</sup> Rather, undue experimentation is used as a reasonableness standard, giving due regard to the nature of the invention and the state of the art.<sup>90</sup> "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed."<sup>91</sup>

At one extreme, a specification need not be so extensive that absolutely no experimentation is needed by one of ordinary skill in the art.<sup>92</sup> As for the other extreme, a specification is clearly insufficient if it only discloses that an invention has been discovered and leaves it to those interested to discover for themselves how to make and use the invention.<sup>93</sup> *In re Kropp*,<sup>94</sup> one of the earliest biotechnology cases, is representative of the undue experimentation extreme. *Kropp* is an appeal by the patent applicant from a final rejection of the patent application based in part on a 35 U.S.C. § 112 rejection for inadequate disclosure of a *Streptomyces* bacterium isolated from a Pennsylvania farm soil sample.<sup>95</sup> The Court of Customs and Patent Appeals defined the disclosure standard as enabling one skilled in the art to "reproduce the invention from the description [in the specification] without *unreasonable* experimentation or without the exercise of inventive skill."<sup>96</sup> The court found that the organism could not be reproduced from the specification without unreasonable experimentation since no source of the organism was provided. The applicants argued that the methods for finding the organism were known in the art and that the specification provided enough details to enable one to identify another culture of the same organism once it was isolated. The applicant asserted that "a screening program could not properly be referred to as experimentation, since it would only involve routine and known procedures."<sup>97</sup> The court rejected this argument, stating that it "would be experimentation to employ the same type of routine and known procedures followed in discovering new antibiotics in the first place."<sup>98</sup> In *Ex parte Jackson*, the Board of Patent and Trademark Appeals affirmed *Kropp*, stating that it was an established fact that organisms newly isolated from nature had to be deposited per se in order for the disclosure to be enabling.<sup>99</sup>

The Federal Circuit did not cite *Kropp* in the *Amgen* decision, but rather distinguished inventions involving the isolation of organisms from nature from genetic engineering inventions. Citing *In re Argoudelis*,<sup>100</sup> the court stated that the practice of placing organisms in public depositories arose out of the development of antibiotics produced from microorganisms from soil samples.<sup>101</sup> The court distinguished inventions using newly isolated, naturally occurring organisms from inventions involving the insertion of genetic material into a publicly available cell line. "When a biological sample required for the practice of an invention is obtained from nature, the invention may be incapable of being practiced without access to that organism. Hence the deposit is required in that case. On the other hand, when the organism is created by insertion of genetic material into a cell obtained from generally available sources," a written description is sufficient.<sup>102</sup> The court gave no scientific support for making this distinction.

While distinguishing between isolating organisms from nature and genetically engineering organisms provided the Federal Circuit with a tidy way of distinguishing the holdings in *Kropp* and *Argoudelis*, it is unclear whether this distinction is scientifically warranted, especially with regard to the best mode. A written description of how to obtain an organism from nature specifies where to obtain the soil sample and then only provides "an experimental screening program similar to the screening programs followed in discovering the organism in the first instance."<sup>103</sup> Similarly, a written description for how to produce a genetically engineered product describes the experimental procedure for creating the product and how to screen for the desired product. The court in *Ex parte Jackson* found the screening process to require undue experimentation since "if the micro-organism involved were of very common occurrence, it might be found in a relatively short time, but if it were not of common occurrence, it might not be found for a very long time, if found at all."<sup>104</sup> The same can be said of materials produced by genetic engineering. This is especially true of the best mode embodiment which, by definition, possesses a more specific set of biological properties.

In *In re Wands*,<sup>105</sup> the first Federal Circuit decision applying the "undue experimentation" standard to genetic engineering, the court distinguished genetically engineered organisms from materials isolated from nature.<sup>106</sup> The patent application in *Wands* claimed a method for conducting an immunoassay that tests for hepatitis B surface antigen using monoclonal antibodies.<sup>107</sup> In order to prepare monoclonal antibodies to hepatitis B surface protein, applicants used mice as the starting material of the invention. Hybridoma cells that secrete monoclonal antibodies that bind to the hepatitis B surface protein were created from lymphocyte cells generated by these mice. The court considered whether the written specification describing how to create and isolate the hybridoma cells, which produce the monoclonal antibodies that bind to the hepatitis B surface protein, was enabling.<sup>108</sup>

The court focused on the issue of whether "it would require undue experimentation to make the cells of the invention from the starting materials."<sup>109</sup> The court evaluated the enablement question as a question of law, substituting its judgment for the conclusion of the Board of Patent Appeals and Interferences,<sup>110</sup> and concluded that undue experimentation was not necessary to obtain the desired monoclonal antibodies by following the specification.<sup>111</sup> The court emphasized that the undue experimentation standard focuses on the word "undue."<sup>112</sup> What constitutes undue experimentation must be evaluated under a "standard of reasonableness having due regard for the invention and the state of the art."<sup>113</sup> As a test for what is "undue," the Federal Circuit adopted and applied the eight factors originally introduced in *Ex parte Forman*.<sup>114</sup> After evaluating the record, the court concluded that the disclosure provided by the application provided considerable direction and guidance on how to practice the invention. Finding the procedures described in the specification neither "unpredictable or unreliable," the court concluded that the specification was enabled.<sup>115</sup>

The technology involved in *Wands*, the production of monoclonal antibodies to a specific antigen, lends itself to the court's conclusion. The invention in *Wands* only required the production of a high affinity antibody to the hepatitis B surface protein. The invention did not require the creation of any specific antibody, only one that would bind to the hepatitis B surface protein.<sup>116</sup> In this sense, the *Wands* invention is more similar to the invention in *Gay* than to that in *Jackson*. In *Gay*, the best-mode rice container had a staggered perforation design making it tear-resistant. The court found in *Gay* that the best mode was adequately reproducible from the specification because the staggered perforation design that distinguished the best-mode embodiment from the other possible embodiments was easily reproduced from the specification.<sup>117</sup>

The issue of whether an inventor needs to deposit the cell line used in the best-mode embodiment was not addressed in *Wands* because the applicants deposited a hybridoma cell line that secretes IgM antibodies against the hepatitis B surface protein.<sup>118</sup> By depositing the best-mode cell line rather than arguing the sufficiency of a written disclosure, the applicants in *Wands* implicitly acknowledged that more than a written disclosure is necessary to enable one of ordinary skill to recreate the specific hybridoma cell line that the applicants' considered best for conducting the immunoassay.

As discussed above,<sup>119</sup> the Federal Circuit presently does not require exact duplication as the standard for disclosure of the best mode cell line. After *Amgen*, applicants like *Wands* no longer have to deposit their best-mode cell lines in order to satisfy the best mode requirement. In fact, two months later, in *Scripps Clinic & Research Foundation v Genetech, Inc.*,<sup>120</sup> the Federal Circuit held that a

patent claiming a process similar to the process in *Wands* was enabled by a written description of the best-mode embodiment, even though the best mode cell line was not deposited.<sup>121</sup>

Over the years, the courts have become more and more reluctant to require the deposit of biological material as a prerequisite to satisfying the undue experiment element of the enablement requirement. In 1959, when *Kropp* was decided, it was accepted that organisms that are not publicly available needed to be deposited in order for the specification to be enabling. In 1986, the enablement of a written disclosure describing a genetically engineered organism was reviewed for the first time by the Board of Patent Appeals and Interferences.<sup>122</sup> The Board found the art insufficiently reproducible for the specification to be enabling.<sup>123</sup> Two years later, the Federal Circuit, in a case of first impression, found a written specification for how to create a genetically engineered organism sufficiently reproducible to satisfy the enablement requirement.<sup>124</sup> In 1991, in a case of first impression, the Federal Circuit ruled that a genetically engineered cell line used in the best mode embodiment need not be deposited in order to satisfy the first paragraph of § 112.<sup>125</sup> Based on the Federal Circuit's decision in *Amgen*, it appears as though the science of biotechnology has matured in the eyes of the court in such a way that special accommodations are no longer necessary to assure the reproducibility of the patent disclosure.<sup>126</sup> The question remains whether this conclusion is warranted.

The court's reproducibility conclusion is supported neither by the scientific community nor by the government.<sup>127</sup> Scientific journals still require authors either to deposit any organisms used to perform the research being disclosed, or to agree to make the organisms available to other investigators.<sup>128</sup> The United States government has also recognized the importance of biological deposits as a means of insuring the free flow of information among the research community.<sup>129</sup> The government requires biological deposits as a condition of funding because, otherwise, such materials "are not truly accessible to the scientific community." "Restricted availability of unique resources upon which future studies are dependent can impede the advancement of research and the delivery of medical care."<sup>130</sup>

It was customary, at least prior to *Amgen*, "for patent applicants to place microorganism samples in a public depository when such a sample is necessary to carry out a claimed invention."<sup>131</sup> The first patent applicant to deposit a biological sample did so in 1949.<sup>132</sup> The practice of making biological deposits was not challenged as a requirement for satisfying the disclosure requirements until 1970.<sup>133</sup> Since 1949, the American Type Culture Collection (ATCC) alone has accepted over 9000 samples from patent applicants.<sup>134</sup> Even *Amgen*, the party which the Federal Circuit ruled did not have to deposit its best mode cell line in order to satisfy the best mode requirement, *voluntarily* deposited two strains of organisms as part of its patent application.<sup>135</sup>

Borrowing from copyright law, it is axiomatic that "the world goes ahead because each of us builds on the work of our predecessors. A dwarf standing on the shoulders of a giant can see farther than the giant himself."<sup>136</sup> The height biotechnology inventors may reach in order to envision new inventions depends on whether the PTO and the courts secure for the public truly adequate, reproducible patent disclosures. The preceding discussion identifies certain flaws in the present disclosure standard, which call into question the effectiveness of the disclosure standard-especially with regard to the best mode requirement. Adoption of a deposit requirement is a plausible method of insuring that adequate disclosures are in fact obtained. The desirability of adopting a deposit requirement for motivating innovation is discussed in part IV.

#### **IV. POLICY IMPLICATIONS OF REQUIRING BIOLOGICAL DEPOSITS**

The comparison of a patent to a contract between an inventor and society provides an excellent framework for evaluating the policy considerations surrounding the disclosure requirement. A patent resembles a unilateral contract in which society agrees to grant a seventeen-year monopoly to any inventor who satisfies the substantive and procedural requirements associated with obtaining a patent. In order for rational actors to want to enter into a contract, the benefit of the contract to each party must exceed the respective costs. The same is true of the patent system. The cost to society of granting monopolies to inventors must be justified by the benefit derived from the inventors' disclosure. Part IV.A discusses how a deposit requirement would assure that the public received its bargained-for disclosure.

Inventors must also be satisfied by the benefits they derive from obtaining patents. Otherwise, inventors will protect their inventions by other methods, such as trade secret. The formula for Coke is the classic example. Had Coca Cola gotten a patent instead of a trade secret, Coke would now be "off patent" and everyone would know the formula for Coke. Biological deposits have been criticized for increasing the cost of obtaining patents, which in effect shifts the cost-benefit balance of obtaining a patent. In addition, biological deposits have been criticized for increasing the risk of piracy of biotechnology inventions. Part IV.B addresses whether a biological deposit requirement will dissuade inventors from applying for patents by making the costs and risks of obtaining a patent outweigh the expected benefits.

Contracts exist because it is sometimes more efficient to pay another party to perform a certain task. The patent system also operates

on this assumption since it assumes that it is cheaper for society to grant a seventeen year patent monopoly in exchange for the patent disclosure than it is for society to innovate without the benefit of patent disclosures. Biological deposits enhance the efficiency of patents by avoiding the need for the costly reinvention of necessary biological material. The economic efficiency argument regarding biological deposit requirements is discussed in part IV.C.

Finally, patents are similar to contracts in the sense that they stabilize the owner's interests in technology, thus facilitating the attraction of capital investment. Biological deposits enhance the stability of patents by effectively removing a basis upon which they can later be found to be invalid. This stabilizing effect is discussed in part IV.D.

### **A. Requiring Biological Deposits Minimizes the Use of Trade Secrets as a Means of Protecting Biotechnology Inventions**

The patent laws were designed to motivate the disclosure of inventions and reduce the use of trade secrets as a method of protecting intellectual property. When the Supreme Court first considered whether new organisms are patentable subject matter under 35 U.S.C. § 101,<sup>137</sup> it was argued that recognizing the patentability of new organisms would give inventors a device for protecting their proprietary biological materials other than trade secret law.<sup>138</sup> Protecting proprietary cell lines as trade secrets "tends to stifle the free exchange of technology and hinders the progress of science by postponing the benefits to mankind of these technologies."<sup>139</sup> In exchange for the right to patent new organisms, the public was to *acquire* the new organisms. There is little doubt that the caliber of disclosure anticipated was the public deposit of these organisms.<sup>140</sup> The government shared this view.<sup>141</sup> However, by not expressly requiring a deposit, the courts have allowed the biological deposit requirement to become a question of enablement to be determined on a case-by-case basis.<sup>142</sup>

In practice, it is the PTO that makes the case-by-case assessment of enablement. A strict disclosure requirement is especially necessary because of the non-adversarial nature of the patent application process. With the exception of interferences,<sup>143</sup> the patent application process is completely *ex parte*.<sup>144</sup> Thus, the PTO is the only party capable of advocating the public's interest.<sup>145</sup> If the patent applicant persuades the examiner that the disclosure is enabling without a biological deposit, that conclusion is presumed to be correct.<sup>146</sup>

The disclosure standard must be designed to protect the public, who in fact cannot reproduce a biotechnological invention based on the specification. Researchers who attempt to reproduce an invention based on a patent disclosure are unlikely to seek the invalidation of a patent if their reproduction efforts prove futile. These members of the public are left with no recourse for obtaining the appropriate level of disclosure. The patent disclosure standard for biotechnology should be designed to safeguard the interests of the silent scientific community at large—not the interests of alleged patent infringers.

The patent applicant has strong economic incentives for keeping proprietary biological material secret.<sup>147</sup> Obtaining patent rights on an invention while retaining an effective trade secret gives the inventor not only a monopoly over the invention, it also makes it more difficult for one to pirate the invention since the materials needed to practice the invention are not provided. Therefore, it is reasonable to expect patent applicants to curtail disclosure wherever possible. The Federal Circuit's *Amgen* opinion has been accused of motivating this result.<sup>148</sup>

If the patentee succeeds in persuading the examiner that the disclosure is enabled without a deposit when the disclosure is, in fact, not enabled, the patentee is able to retain a trade secret on the claimed biological material without forgoing patent protection. If a court later decides that the specification is not enabling, the patentee loses her patent protection, but still possesses the trade secret. Recent decisions indicate that the courts are unlikely to find the specification non-enabled,<sup>149</sup> especially after the PTO finds the disclosure enabling. This is in part due to the contradiction involved in finding the specification is not enabled when the infringer has reproduced it.<sup>150</sup> Written as something of a response to an increase in best-mode defense cases, Judge Newman stated that "patent applications rarely contain every detail for that is not their function, but infringers constantly seek to enlarge any omission into a fatal flaw. Challenge is easy; the penalty is extreme. Thus precedent requires that violation of the best mode requirement be established by clear and convincing evidence."<sup>151</sup>

An even greater danger exists when the public is not able to practice the invention absent a deposit. In these situations, infringement is not possible and therefore cannot serve as a vehicle for raising a non-enablement argument. In such situations, the patent holder maintains her trade secret while receiving an insurance policy in case the public eventually learns how to practice the invention. The exchange of information that the public bargained for is never received. The primary goal of the patent system is the public disclosure of inventions, not the patent rights that are granted.<sup>152</sup> Therefore, the disclosure rules should be tailored to prevent the patentee from keeping biological material necessary for practicing the invention as a trade secret when a patent is granted.

One solution for counteracting the industry participants' self interests in minimizing disclosure is the construction of bright line disclosure requirements. With an over-burdened patent office,<sup>153</sup> it is in the public's interest to have a conservative bright line rule for enablement, since that enables the PTO to police patentee compliance with the disclosure requirements more efficiently.<sup>154</sup> Requiring the patentee to deposit the biological material necessary for practicing the invention achieves this objective.

## **B. The Cost to the Patentee of Making Biological Deposits**

There are two arguments that have been raised against adopting a biological deposit requirement. The first is that a biological deposit requirement would significantly increase the cost of obtaining a patent. It presently costs roughly one thousand dollars to deposit a microorganism with the American Type Culture Collection.<sup>155</sup> The cost of prosecuting a patent, aside from the cost of making a deposit, ranges from \$5,000 through \$15,000, depending on the complexity of the invention and the crowdedness of the relevant art. Thus, the cost of making a deposit can be a substantial portion of the cost of obtaining a patent. This is especially true when more than one deposit is necessary to enable a specification.<sup>156</sup> Advocates against a deposit requirement have cautioned that the cost of making biological deposits may discourage some inventors, especially small startup companies, from obtaining patent protection, or from even pursuing the research necessary to develop the invention.<sup>157</sup>

While a deposit requirement may increase the cost of obtaining patent protection, a deposit requirement should also decrease the cost of doing research by enabling inventors to avoid reinventing the wheel.<sup>158</sup> This cost savings should more than adequately compensate industry members for the added costs of obtaining patent protection caused by a deposit requirement. This note proposes a deposit requirement for the best mode embodiment. By limiting the requirement to the best mode, the cost of compliance is minimized, since only one deposit would be required. At the same time, the benefit to society is maximized since the best mode is guaranteed to be adequately and reproducibly disclosed.

The other objection inventors have against a biological deposit requirement is that it facilitates the piracy of inventions, particularly abroad.<sup>159</sup> The argument has been called the super recipe argument because deposits are said to provide a super recipe that makes it too easy to infringe the patented invention.<sup>160</sup> By facilitating infringement, the deposit requirement undermines the benefit provided by a patent monopoly and thus motivates the use of trade secret protection by inventors.<sup>161</sup> Not making a deposit enables the patentee to limit the availability of the biological material necessary for practicing the invention by remaining the only source of that material. Biological materials that are deposited are often self replicating and thus easily transferred. Much like computer software, samples of the biological material can be rapidly and cheaply copied. Limiting a patent's disclosure to a written description serves as a form of copy protection for the patentee.

The argument that limiting the patent disclosure to a written disclosure enables the patentee to retain control over the invention exposes the flaw of the super recipe argument. The patent specification should enable one of ordinary skill in the art to practice the invention. A patentee cannot justify not making a deposit on the grounds that making that deposit would place the invention in the public's hands. In a sense, the super recipe argument is an admission that a purely written disclosure is unreasonable, since withholding the patented material makes it significantly more difficult to practice the invention. If making a deposit causes a patentee to lose control over the invention, the proper solution is enhancing the effectiveness of the patent enforcement regime rather than diluting the disclosure requirements.

Congress has made inroads into strengthening patent protection for process patents. Prior to the passage of the Omnibus Trade and Competitiveness Act of 1988<sup>162</sup> (the "Act"), products that were produced abroad by a process that infringes a U.S. patent could be imported. This meant that a party could obtain the biological material used in a process patent from a depository, practice the process patent abroad, and import a product produced by that process patent into the United States without infringing the process patent. This loophole was somewhat closed by the 1988 Act. The Act created 35 U.S.C. § 271(g)<sup>163</sup> which provides a cause of action for infringement for the importation, sale or use of any product that is produced by a process that infringes a U.S. patent.

There is now pressure on Congress to extend the statute further so that it covers materials made by patented organisms.<sup>164</sup> This pressure was inspired by the Amgen dispute. Since Amgen's patent covers the host cell transformed by the addition of the EPO gene, rather than the process of making EPO, Amgen cannot prevent the importation of EPO produced abroad by Amgen's host cells.<sup>165</sup> Extending § 271(g) to cover materials produced by patented organisms would help to close this importation loophole. The social and economic desirability of extending the statute in this manner is presently being debated and is beyond the scope of this paper. What is certain is that the patent disclosure requirements should not be sacrificed. The cost to the inventor of making an enabling disclosure should be minimized by fortifying the patent enforcement laws.

## **C. The Public's Economic Incentive in a Deposit Requirement**

Regardless of whether a deposit is necessary to satisfy the enablement requirement, the public and the industry as a whole have a strong economic incentive to require the deposit of biological organisms used in patented processes. Not using biological deposits as a method for disclosure creates an unnecessary expense. Even if the PTO is able to police compliance with the disclosure requirements so that all written disclosures are enabling, requiring the public to reinvent the wheel every time a different individual chooses to practice the invention wastes innovation resources through the duplication of efforts. It presently costs about \$1000 to deposit a biological sample and have it maintained for thirty years.<sup>166</sup> Once deposited, the biological material is available to the public at a fee of forty-five through ninety dollars per culture.<sup>167</sup> This cost is nominal when compared to the cost of reproducing the same material from a written specification.<sup>168</sup> In 1993, the federal government will spend four billion dollars for biotechnology research, a seven percent increase over 1992.<sup>169</sup> With the faltering world economy and our country's rising debt, legislation requiring patent applicants to make biological deposits is a rational cost-saving measure. Adoption of a deposit requirement is likely to provide further savings by allowing companies to redirect spending from rediscovery to innovation.<sup>170</sup>

#### **D. Patent Right Stability**

Biological deposits also assure patent stability since biological deposits are the most certain means known for assuring compliance with the enablement requirement of § 112.<sup>171</sup> Firms are inherently motivated not to make biological deposits in the interest of retaining control over their biological material, and in avoiding the costs associated with making biological deposits. This may tempt some patent applicants to risk patent invalidity due to a non-enabled written specification by providing only a written disclosure. The foreseeable result is a decrease in the stability of patent interests in biotechnology. An enablement requirement subject to vague conditions like "adequate disclosure"<sup>172</sup> and "undue experimentation"<sup>173</sup> promotes an increase in litigation. When companies spend more money on litigation, less funds are available for research.<sup>174</sup> Litigation reduces profitability, thus diverting investment capital.<sup>175</sup>

Leaving the question of patent validity to the courts dramatically increases the volatility of a biotechnology company's stock. The *Amgen* dispute is a prime example. Erythropoietin (EPO), the drug at issue, has an estimated market value in excess of \$500 million annually.<sup>176</sup> News of the Federal Circuit's decision drove Amgen's stock up twenty percent while Genetics Institute's stock dove by thirty-three percent.<sup>177</sup> As blockbuster drugs become more commonplace, patent disputes may frequently become "bet the company scenarios." It is unclear whether the biotechnology industry as a whole can support these types of value assessment swings, especially in light of the regulatory hurdles that these companies already face. Thus, reasonable patent certainty is essential if biotechnology is to expect continued influx of investment capital, the lifeblood of this emerging industry.

#### **V. CONCLUSION**

Based on a reasonableness standard for undue experimentation, some rule requiring the biological deposit of genetically engineered organisms used in patented processes should be statutorily required. In *Wands*, the Federal Circuit adopted several factors to consider when determining whether undue experimentation is required to practice an invention.<sup>178</sup> Noticeably absent from these factors, especially since undue experimentation is a reasonableness standard, is a best feasible disclosure requirement. The emphasis in "undue experimentation" is on "undue."<sup>179</sup> Failure to provide a disclosure that minimizes the need for experimentation seems undue, and unreasonable, when a better form of disclosure is known and readily available. If public disclosure and use of an invention is truly the "centerpiece of federal patent policy,"<sup>180</sup> then the reasonableness of a disclosure ought to be measured against whether the applicant used the best means available for disclosing the invention. If a better disclosure is known and reasonably available, failure to provide that better disclosure should violate the undue experimentation standard.

Applying a best disclosure requirement to most technologies is unworkable because it encourages litigation over how well an applicant described an invention rather than whether the disclosure was enabling. However, for biotechnology inventions, a best disclosure requirement in the form of a deposit requirement would be both functional and desirable. A deposit requirement is functional because it is easily and clearly satisfied when the inventor deposits the biological material used in the invention. Biological deposits ensure the stability of biotechnology patents since they reduce the avenues for attacking a patent's validity. A deposit requirement is also socially desirable because it reduces research costs by minimizing the need for experimentation to reproduce the parent invention.<sup>181</sup>

Presently, biological deposits are required to satisfy the enablement and best mode requirements of 35 U.S.C. § 112, either directly or indirectly. The PTO guidelines provide that "biological material need not be deposited, inter alia, if it is known and readily available to the public or can be made or isolated without undue experimentation."<sup>182</sup> Biological material is considered "known and readily available to the public" when it is deposited in an acceptable depository.<sup>183</sup> This provision effectively provides that one need not deposit material that has already been deposited. Biological material that "can be made or isolated without undue experimentation" presupposes that the starting materials necessary for conducting the experiment are "known and readily available to the public."<sup>184</sup> While these guidelines require that the starting material used to create the new and essential biological material be available to the

public,<sup>185</sup> generally by being on deposit, the inventor is not required to make the biological material that is essential to practicing the invention publicly available. Therefore, these guidelines do not require the best disclosure possible. They only require a disclosure that is enabling without undue experimentation.

There is reason to doubt the effectiveness of the undue experimentation standard as it is applied to biotechnology. Reading *Jackson*, *Forman*, *Wands*, *Amgen*, and *Scripps* in succession, it is apparent that the courts are inclined to start treating biotechnology as a mature science which may be readily reproducible from written descriptions. However, it is unclear whether such treatment is premature. Judge Newman noted in *Wands* that "as the science of biotechnology matures the need for special accommodation, such as the deposit of cell lines and microorganisms, may diminish."<sup>186</sup> For the purpose of motivating innovation, it is important not to remove the special accommodations made for biotechnology prematurely. In light of the policy reasons set forth above, there appears to be little reason not to treat biotechnology special by requiring biological deposits until such time when it is certain that biotechnology is well established and reproducible.

Pursuant to a best disclosure requirement rationale, and in light of all the policy issues involved, Congress should enact a rule requiring the deposit of any publicly unavailable biological material that is used in the best mode embodiment of a patent. The breadth of the proposed rule is justified in the sense that the best mode requirement inherently requires a higher level of reproducibility, thus justifying a higher disclosure standard than the enablement requirement. Since the best mode requirement requires the enablement of the mode that the inventor subjectively believes is the best mode, the statute provides the applicant with adequate direction with regard to what material must be deposited.<sup>187</sup> The proposed rule also serves as a procedural guarantee that the "best" mode, frequently the most valuable mode, will be enabled. Finally, the proposed rule renders moot the argument that one can conceal the best mode and at the same time provide an enabling of the best mode.

Even when biotechnology matures, biological deposits may still provide the most efficient and socially desirable means of disclosing an invention. Uniform application of a deposit requirement should increase patent stability and reduce research and development expenditures. With more information available to the public and more money to exploit that information, innovation will be facilitated rather than squelched.

Whether undue experimentation is required to practice an invention is unavoidably a fact dependent determination.<sup>188</sup> As a factual inquiry, a great deal of jury discretion is interposed that can potentially be unduly influenced by ancillary factors such as unclear hands, jury confusion regarding the technology and hindsight based decision making. As the monetary interests in patents increase, it becomes more and more important to safeguard the patent disclosure requirements where possible.

In general, there is little reason not to require the deposit of biological organisms, especially in light of recent legislation preventing the import of products made abroad by patented processes.<sup>189</sup> Without significant counterbalances weighing against a biological deposit rule, the benefits of a deposit requirement clearly outweigh the associated burdens. This is especially true if the mandatory deposit rule is limited to the best mode embodiment of the invention. The courts, with the *Amgen* decision, have reached a natural resting ground in the evolution of the biological deposit issue. Therefore, it is up to the legislature to introduce a deposit requirement. Based on the strong response supporting Genetics Institute's writ for certiorari on the deposit issue, it is quite likely that the legislation proposed here will be warmly welcomed.

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1. S. Chesterfield Oppenheim, *A New Approach To Evaluation Of The American Patent System*, 33 J. PAT. OFF. SOC'Y 555, 555 (1951) ("The United States has staked its national destiny and welfare upon the basic principle that private initiative, creative talents and venture capital shall be the primary means of determining the recipients of rewards for competitive enterprise. The American Patent System is deeply imbedded in that tradition.").

2. U.S. NATIONAL PATENT PLANNING COMM'N, *THE AMERICAN PATENT SYSTEM*, H.R. Doc. No. 239, 78th Cong., 1st Sess. 1, at 783-84 (1943) ("The American patent system established by the Constitution giving Congress the 'power to promote the progress of science and useful arts,' is over [200] years old. The system has accomplished all that the framers of the Constitution intended. It is the only provision of the government for the promotion of invention and discovery and is the basis upon which our entire industrial

civilization rests.").

3. U.S. CONST. art. I, § 8, cl. 8. ("The Congress shall have power . . . to promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.").

4. *Graham v. John Deere Co.*, 383 U.S. 1 (1966) ("Congress quickly responded to the bidding of the Constitution by enacting the Patent Act of 1790 during the second session of the First Congress. It created an agency in the Department of State headed by the Secretary of State, the Secretary of the Department of War and the Attorney General, any two of whom could issue a patent for a period not exceeding 14 years to any petitioner that 'hath . . . invented or discovered any useful art, manufacture . . . or device, or any improvement therein not before known or used' if the board found that the invention or discovery [was] sufficiently useful and important.").

5. *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 146 (1989) ("From their inception, the patent laws have embodied . . . the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.").

6. *Id.* at 156.

7. *United States v. Masonite Corp.*, 316 U.S. 265, 278 (1942).

8. REPORT OF THE PRESIDENT'S COMM'N ON THE PATENT SYSTEM (U.S. Gov't Printing Office 1966), *quoted in* Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. OFF. SOC'Y 617, 642 (1985); *see also* Albert P. Halluin, *Courts Might Be Locking Up Cures*, S. F. EXAMINER, Feb. 12, 1992, at 1 (criticizing the present biological deposit requirement for inhibiting disclosure and thus impeding the scientific community's progress in the development of an AIDS vaccine).

9. Rebecca S. Eisenberg, *Proprietary Rights and Norms of Science in Biological Research*, 97 YALE L.J. 177, 229 (1987).

10. 35 U.S.C. § 112 (1988).

11. Ann Thayer, *Huge Growth Forecast for Biotech Markets*, CHEM. & ENG. NEWS, Feb. 10, 1992, at 20-21.

12. 927 F.2d 1200 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

13.

If a patent applicant knows that he can receive a patent monopoly while keeping his best mode cell line as a trade secret, he or she has no incentive to place samples of that cell line in a public depository. It is reasonable to assume that the practice of withholding the best mode biocultures will become widespread. Consequently, the flow of vital biological resources on which research and advancement in genetic engineering depend will diminish.

Amicus Brief for the American Type Culture Collection in Support of Petition for Certiorari at 6, *Amgen* (No. 91-13), (citing Albert P. Halluin, *Amgen & Scripps: The New Biotechnology Practice*, 10 BIOTECHNOLOGY LAW REPORT 191, 208 (1991)).

14. See *infra* part II for a description of what deposits are and the role they play in the scientific community.

15. *Amgen*, 927 F.2d at 1210. This Article focuses on the question of enablement. However, as discussed *infra* note 61, the *Amgen* decision raised several other issues with regard to satisfying the best mode requirement.

16. *Amgen*, 927 F.2d at 1211. See *infra* part III.B for a discussion of the undue experimentation standard.

17. 37 C.F.R. § 1.802(b) (1993).

18. See *infra* part II for a discussion of the biological deposits.

19. 37 C.F.R. § 1.802(b) (1993).
20. *Id.*
21. *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988).
22. *Atlas Powder Co. v. E. I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984).
23. Amicus Brief for The Taxpayers Assets Project of the Center for Study of Responsive Law in support of Petition for Certiorari at 2, *Amgen* (No. 91-13).
24. Amicus Brief for Roger Sperry et al. in Support of Petition for Certiorari at 4, *Amgen* (No. 91-13) ("The Federal Circuit has threatened progress and competition in the field of biotechnology with its ruling that a genetic engineer may keep a patent monopoly even while refusing to make deposits of his unique cell lines or other newly created biological materials, thereby withholding those vital research resources from the public and the scientific community."); *Id.* at 3, ("The Federal Circuit's decision in this case alters the bargain struck by Congress between the public and inventors by allowing inventors of genetically engineered cell lines to withhold the exact nature of those cell lines from the public."); Amicus Brief for The Council For Responsible Genetics in Support of Petition for Certiorari at 9, *Amgen* (No. 91-13) ("It is, *as a matter of law*, inescapable that an inventor's "best mode" can *never* be accomplished without the deposit of genetically altered cells. This is in fact what Congress has required. . . . [T]he realities of biomedical science compels the conclusion that the clearly expressed aim of Congress-that inventors fully and completely disgorge the secrets of their invention-requires [a] deposit, and sensibly so. The Federal Circuit's decision amounts to judicial legislation which, at least in this one decision, cuts to the very core of Congressional, and Constitutional intent.") (emphasis in original); *see* Amicus Brief for The American Type Culture Collection in Support of Petition for Certiorari at 11, *Amgen* (No. 91-13) (The Federal Circuit decision threatens to stifle the useful arts of biotechnology, rather than to promote them.).
25. OFFICE OF TECHNOLOGY ASSESSMENT, *COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 3* (1984).
26. For a summary of what is biotechnology, see WULF CRUEGER & ANNELIESE CRUEGER, *BIOTECHNOLOGY: A TEXTBOOK OF INDUSTRIAL MICROBIOLOGY* (2d ed. 1989); ROBERT WILLIAMSON, *GENETIC ENGINEERING* (1982).
27. IVER COOPER, *BIOTECHNOLOGY AND THE LAW* § 1.02 (1991). ("A written description of a novel organism in a patent specification is of little aid to other scientists if that microorganism is not available through a public depository."), *quoted in* Petition for Writ of Certiorari at 21, *Amgen* (No. 91-13).
28. Amicus Brief for The American Tissue Type Culture Collection in Support of Petition for Certiorari at 4, *Amgen* (No. 91-13).
29. *Notice to Authors*, *VIROLOGY*, Jul. 1991, at vii ("Nucleotide Sequence Data"); *see also Information for Contributors*, *SCIENCE* Mar. 28, 1986, at xi ("Conditions of Acceptance").
30. DEPT. HEALTH & HUMAN SERVICES (OASH) PUBLICATION NO. 90-50.000 at 8-24 (Rev. Oct. 1, 1990), *quoted in* Amici Brief of American Foundation for AIDS Research et al. in Support of Petition for Writ of Certiorari, *Amgen* (No. 91-13).
31. Biological depositories also function as research organizations in the sense that they disclose information that they learn about the cultures on deposit through scientific publications and workshops. OFFICE OF TECHNOLOGY ASSESSMENT, *NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE* 141 (1989) [hereinafter *NEW DEVELOPMENTS*].
32. For a review of how deposits are maintained, see *id.* at 147-50.
33. The present fees for making a deposit with the American Type Culture Collection (ATCC) are as follows:

30 years' storage \$570

30 years' notification of requesters \$300

Viability testing:

Microorganisms, cells,

hybridomas and seeds \$100

Animal embryos \$200

Viruses and plasmids (not in a host) Quoted Individually

ATCC to furnish supply of additional

ampules of cells or hybridomas \$350

AMERICAN TYPE CULTURE COLLECTION, GUIDE TO MAKING PATENT DEPOSITS, (1992).

34. Procuring a sample from a depository generally only requires sending in a request along with the depository's fee. The American Type Culture Collection presently charges a fee of \$45-90 a culture. For a good description of biological depositories and their operation, see NEW DEVELOPMENTS, *supra* note 31, at 147-50.

35. AMERICAN TYPE CULTURE COLLECTION, *supra* note 33, at 11.

36. U.S. Pat. No. 2,483,892 issued October 4, 1949. In August 1949, American Cyanamid deposited a culture of *Streptomyces aureofaciens* with the Agriculture Research Service Culture Collection now known as the Northern Regional Research Laboratory in conjunction with its application for U.S. Pat. No. 2,482,055 which was issued September 13, 1949.

37. *See infra* part IV.B.

38. It is somewhat ironic that the self regulating scientific community has taken the stricter draconian approach and the government regulated patent system has taken the less stringent approach.

39. Feldman v. Aunstrup, 517 F.2d 1351, 1355 (C.C.P.A. 1975) (the depositing of a microorganism to comply with the provisions of 35 U.S.C. § 112 is not a rule of law), *cert. denied*, 424 U.S. 912 (1976); Merck & Co. v. Chase Chemical Co., 273 F.Supp. 68 (D.N.J. 1967); *In re* Argoudelis 434 F.2d 1390 (C.C.P.A. 1970).

40. 37 C.F.R. § 1.802(b) (1993); *In re* Interference A v. B v. C, 159 U.S.P.Q. (BNA) 538, 540 (Commr. PTO 1967) ("[A]pplicant does not need to teach in his specification how to make or obtain already known materials or ingredients.").

41. *Ex parte* Forman, 230 U.S.P.Q. (BNA) 546, 547 (Bd. Pat. App. & Intf. 1986) (The "undue experimentation" proscription is, in effect, a gloss on the statute which has arisen from decisional law which requires that sufficient information be given in the application so that one of ordinary skill in the art can practice it without the necessity for undue experimentation.).

422. Century Elec. Co. v. Westinghouse Elec. & Mfg. Co., 191 F. 350 (8th Cir. 1911).

43. Grant v. Raymond, 31 U.S. (6 Pet. ) 218 (1832).

44. *In re* Lundak, 773 F.2d 1216, 1221 (Fed. Cir. 1985).

45. *Id.*

46. 35 U.S.C § 112 (1988).

47. Patent Act of 1870, ch. 230, § 16 Stat. 201 ("[I]n the case of a machine [the inventor] shall fully explain the principle and the best mode in which he contemplated the application of that principle."). This enactment modified the Patent Act of 1793 that required the inventor to fully explain all modes of operation of the experiment that the inventor contemplated. See *In re* Honn, 364 F.2d 454 (C.C.P.

A. 1966) for a discussion of the legislative history behind the best mode requirement.

48. More than one author contends that no case prior to 1965 held a patent invalid for concealing the best mode. *See* William F. Herbert, *Failure To Disclose The "Best Mode": What The Public Doesn't Know Will Hurt Them*, 64 J. PAT. OFF. SOC'Y 12 (1982); Dugald S. McDougall, *The Courts Are Telling Us: "Your Client's Best Mode Must Be Disclosed,"* 59 J. PAT. OFF. SOC'Y 321 (1977).

49. *See* *Flick-Reedy Corp. v. Hydro-Line Mfg. Co.*, 351 F.2d 546 (7th Cir. 1965), *cert. denied*, 383 U.S. 958 (1966).

50. *Dana Corp. v. IPC Ltd. Partnership*, 860 F.2d 415, 418 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989).

51. The best mode need not be the most efficient mode. This Article concludes that what is considered the best mode depends upon the subjective opinion of the inventor.

52. *See infra* note 53.

53. In *Amgen*, the best mode cell line was a "specific genetically-heterogeneous strain of Chinese hamster ovary (CHO) cells, which produced EPO at a rate greater than that of other cells." *Amgen*, 927 F.2d at 1209. This best mode cell line was described in Example 10 of U.S. Pat. No. 4,703,008 entitled "DNA Sequences Encoding Erythropoietin."

54. *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927 (Fed. Cir. 1990).

55. *Id.*

56. *Id.*

57. *Spectra-Physics v. Coherent, Inc.*, 827 F.2d 1524, 1535-36 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987).

58. *Id.* The question of whether an applicant's disclosure is so poor so as to constitute concealment really asks whether the best mode disclosure is enabling. *See In re Sherwood*, 615 F.2d 809 (C.C.P.A. 1980); *Chemcast*, 913 F.2d at 927.

59. *Chemcast*, 913 F.2d at 927.

60. *Amgen*, 927 F.2d at 1210.

61. In *Amgen*, the defendants argued that the failure of the inventor of *Amgen's* patent to deposit the best mode cell line and instead depositing "worthless cell material" was evidence of deliberate concealment. *Id.* at 1212. The Federal Circuit rejected this argument, holding that deliberate concealment of the best mode by failing to deposit the best mode cell line is legally irrelevant if the best mode is enabled by a written disclosure. *Id.* Whether an enabled disclosure of the best mode can be nonetheless concealed is not addressed in this note. For the purposes of this paper, it is presumed that "concealment" means failure to enable the best mode. Adoption of a mandatory deposit rule similar to the one proposed *infra* part V would obviate the need for resolving this other issue.

There is also an issue whether the duty not to conceal the best mode requires the inventor to specifically identify what she conceives of as the best mode. *See Randomex, Inc. v. Scopus Corp.*, 849 F.2d 585, 591 (Fed. Cir. 1988) (Mayer, J., dissenting). This issue is beyond the scope of this paper. Adoption of the rule proposed *infra* section V requiring a deposit in order to comply with the best mode requirement would obviate the need for resolving this issue as well.

62. *Amgen*, 927 F.2d at 1211.

63. *Id.*

64. *Id.* at 1212.

65. "Biological material need not be deposited unless access to such material is necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. § 112. If a deposit is necessary, it shall be acceptable if made in accordance with these

regulations. Biological material need not be deposited, inter alia, if it is known and readily available to the public or can be made or isolated without undue experimentation. Once deposited in a depository complying with these regulations, a biological material will be considered to be readily available even though some requirement of law or regulation of the United States or of the country which the depository institution is located permits access to the material only under conditions imposed for safety, public health or similar reasons." 37 C.F.R. § 1.802(b) (1993).

66. 37 C.F.R. § 1.802(b) does not "address the substantive issue of whether a deposit is required under any particular set of facts." 54 Fed. Reg. 34,864 (1989).

67. 37 C.F.R. § 1.802(b) (1993).

68. *Dana Corp. v. IPC Ltd. Partnership*, 860 F.2d 415, 418 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989).

69. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1532 (Fed. Cir. 1987) (To constitute an adequate disclosure under the first paragraph of 35 U.S.C. § 112, a patent specification must set forth both the manner and process of making and using the invention (the enablement requirement) and the best mode contemplated of carrying out the invention (the best mode requirement).); *In re Sherwood*, 615 F.2d 809, 816-17 (C.C.P.A. 1980) (A disclosure is adequate where it "delineates the best mode in a manner sufficient to require only application of routine skill.").

70. *In re Gay*, 309 F.2d 769, 774 (C.C.P.A. 1962).

71. The court cited the following district court findings regarding reproducibility with approval: "The testimony is clear that no scientist could ever duplicate exactly the best mode used by Amgen, but that those of ordinary skill in the art could produce mammalian host cell strains or lines with similar levels of production identified in Example 10." *Amgen*, 927 F.2d at 1212.

72. *Id.* (citing *In re Gay*, 309 F.2d 769 (C.C.P.A. 1962)).

733. 309 F.2d at 769.

744. *Id.* at 770.

755. *Id.*

76. *Id.* at 773. The specification stated:

The openings need not cover the entire area of the enclosure and may extend through the fold or unseamed margin 12 of the sheet material. The spacing of the openings may vary with the nature of the sheet material to prevent weakening and accidental tearing thereof. Preferably, [indicating the inventor's best mode embodiment], the openings are arranged in intersecting rows 18 extending diagonally or in non-parallel relation to the margins of the enclosure to prevent undue weakening thereof.

*Id.*

77. *Id.*

78. Although not identified as such by the court, the specification describes the best mode as the following: "*Preferably*, the openings are arranged in intersecting rows 18 extending diagonally or in non-parallel relation to the margins of the enclosure to prevent undue weakening thereof." *Id.* (emphasis added). The perforation design described above is very common and can only be assumed to have been known in the art. Furthermore, the number 18 contained within the specification refers to the holes depicted in the drawings accompanying the specification. As the court noted, the drawings accompanying the invention were, "in view of the nature of the invention . . . a very important part of the complete enabling disclosure." *Id.* at 774.

79. *Id.* at 774.

80. *Amgen*, 927 F.2d at 1212.

81. *Id.* at 1211. This commentator reserves judgment on whether *Amgen* was determined correctly on its facts, i.e., whether the best mode was reproducible without undue experimentation. What is noteworthy is the language used to support the decision.

82. The policy issues surrounding whether a mandatory deposit requirement should be established are discussed *infra* part IV.

83. The court interpreted the testimony of Genetics Institute's expert as indicating reproducibility. *Amgen*, 927 F.2d at 1211 ("[W]ith the vectors and the sequences shown in Example 10, I have no doubt that someone eventually could reproduce-well, could generate cell lines [*sic*, strains] making some level of EPO, and *they could be better, they could be worse* in terms of EPO production.") (emphasis in original). However, this same testimony can be read as indicating that there is no guarantee that the disclosure was reproducible.

84. *Amgen*, 927 F.2d at 1210.

85. In *Gay*, the court noted:

Whatever doubt may exist [regarding enablement] must be resolved in appellant's favor in view of the drawings which, in view of the nature of the invention before us, are a very important part of the complete enabling disclosure. We think that they have not been given enough weight in deciding whether the disclosure satisfies this statutory requirement.

*In re Gay*, 309 F.2d 769, 774 (C.C.P.A. 1962).

86. Congress has recognized that words alone are not always sufficient to create an enabling specification of the invention and legislated to give the PTO discretion to require drawings (35 U.S.C. § 113 (1988)), working models (37 C.F.R. § 1.92 (1993)), specimens of chemicals (37 C.F.R. § 1.93 (1993)) and drawings and specimens of asexually propagated plants (37 C.F.R. §§ 1.165-1.166 (1993)) where necessary to comprehend the invention.

87. *In re Ghiron*, 442 F.2d 985, 991 n.5 (1971) ("If the selection of a suitable apparatus requires undue experimentation and delays . . . to come into possession of the apparatus that could carry out the invention, a disclosure thus deficient would not be adequate legal consideration for the grant of a patent.").

88. *See Standard Brands v. National Grain Yeast Corp.*, 101 F.2d 814 (3d Cir.), *aff'd* 308 U.S. 34 (1939) and cases cited within.

89. *See In re Wands*, 858 F.2d 731, 739 n.29 (Fed. Cir. 1988) ("Even if we were to accept the PTO's 2.8% success rate, we would not be required to reach a conclusion of undue experimentation. Such a determination must be made in view of the circumstances of each case and cannot be made solely by reference to a particular numerical cutoff."). *Cf. White Consol Indus. v. Vega Servo-Control*, 713 F.2d 788, 791 (Fed. Cir. 1983) ("[D]evelopment of a single pass language translator would require from 1 1/2 to 2 man years of effort, a clearly unreasonable requirement.").

90. *Wands*, 858 F.2d at 737; *Ansul Co. v. Uniroyal Inc.*, 448 F.2d 872, 878 (2d Cir. 1971), *cert. denied*, 404 U.S. 1018 (1972).

91. *Wands*, 858 F.2d at 737.

92. *Atlas Powder Co. v. E.I. Du Pont De Nemours*, 750 F.2d 1569, 1576 (Fed. Cir. 1984) ("That some experimentation is necessary does not preclude enablement; the amount of experimentation, however, must not be unduly extensive.").

93. *In re Gardner*, 427 F.2d 786, 789 (C.C.P.A. 1970). In *Gardner*, the inventor claimed to have discovered antidepressant activity in 2-aminomethyl-1, 3-benzodioxole compounds. The PTO rejected the patent application because, in part, the specification failed to disclose how to use the invention, i.e. what dosages of the drug are effective. The court found that one skilled in the art could, after "*a great deal of work*," eventually find out how to use the invention. The court held that "the law requires that the disclosure in the application shall *inform* them *how* to use, not how to find out how to use for themselves." *Id.*

94. 143 U.S.P.Q. (BNA) 148 (1959).

95. *Id.* at 151; The bacterium produces an antibiotic which the patent applicant claimed.

96. *Kropp*, 143 U.S.P.Q. at 152. As support for this standard, the court cited the following cases in footnote 1: *Standard Oil Co. of Calif. v. Tide Water Associated Oil Co.*, 154 F.2d 579 (3d Cir. 1946); *Detachable Bit Co. v. Timken Roller Bearing Co.*, 133 F.2d 632 (6th Cir. 1943); *Libby-Owens-Ford Glass Co. v. Celanese Corp. of Am.*, 135 F.2d 138 (6th Cir.), *cert. denied*, 320 U.S. 774 (1943); *Haliburton Oil Well Surveying Corp. v. Schlumberger Well Surveying Corp.*, 130 F.2d 589 (5th Cir. 1942), *cert. denied*, 318 U.S. 758 (1943); *Johns-Manville Corp. v. Ludowici-Celadon Co.*, 117 F.2d 199 (7th Cir. 1941); *Fruit Treating Corp. v. Food Mach. Corp.*, 112 F.2d 119 (5th Cir.), *cert. denied*, 311 U.S. 679 (1940); *Research and Dev. Corp. of Illinois v. Chase*, 88 F.2d 353 (7th Cir. 1937); *United Drug Co. v. Ireland Candy Co.*, 51 F.2d 226 (8th Cir. 1931), *cert. denied*, 284 U.S. 683 (1932); *Cleveland Gas Burner & Appliance Co. v. American Heater Corp.*, 38 F.2d 760 (8th Cir. 1930); *In re Beach*, 152 F.2d 981 (C.C.P.A. 1946); *Standard Brands v. National Grain Yeast Corp.*, 21 F. Supp. 46 (D.N.J. 1937), *modified* 101 F.2d 814 (3d Cir.), *aff'd* 308 U.S. 34 (1939); *Swan Research v. Dow Chem. Co.*, 12 F. Supp. 270 (E.D. Mich. 1935); *In re Stauber*, 45 F.2d 661 (C.C.P.A. 1930).

97. *Kropp*, 143 U.S.P.Q. at 152.

98. *Id.*

99. *Ex parte Jackson*, 217 U.S.P.Q. (BNA) 804 (Bd. Pat. App. & Intf. 1982) raised the issue of whether a claim covering all strains of a newly discovered, naturally occurring species of organisms is enabled by the deposit of three strains of that organism. Applicants deposited three strains of *Micromonospora pilosospora* claiming the process of producing the antibiotic from any strain of the *Micromonospora pilosospora* species. The PTO examiner rejected the claim under 35 U.S.C. § 112. The Board of Patent Appeals viewed the rejection as raising the question of "whether a verbal description of a new species would enable one of ordinary skill in the relevant art to obtain strains of that species over and above the specific strains made available through deposit in one of the recognized culture depositories." *Jackson*, 217 U.S.P.Q. at 806. As for the isolation of new organisms from nature, "the necessity for a deposit *per se* was taken as an already established fact." *Id.*

The board reduced the issue to whether a verbal description of the specification rather than a biological deposit would require undue experimentation to practice the invention.

To determine what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. . . . The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

*Id.* at 807. The court cited *In re Argoudelis*, 434 F.2d 1390, 1394 (C.C.P.A. 1970) at length and came to the conclusion that "only a deposit of a new organism can satisfy 35 U.S.C. § 112 with respect to a process utilizing that organism." *Jackson*, 217 U.S.P.Q. at 809.

100. 434 F.2d 1390 (C.C.P.A. 1970). Like *Kropp*, *Argoudelis* involves a patent application claiming the discovery of a new antibiotic produced by a naturally occurring *Streptomyces* bacterial strain. *Argoudelis* addressed the issue of when biological material used in a patented invention needs to be known to the public for the specification to be considered enabled under 35 U.S.C. § 112. *Id.* at 1392-94. Applicants deposited a strain of *Streptomyces* with the United States Department of Agriculture depository on the condition that the bacterial deposit was not to be made available to the public until the patent issued. *Id.* at 1391. The PTO rejected the application arguing the biological material needs to be available at the time the application is filed in order to satisfy § 112. *Id.* The Court of Customs and Patent Appeals ruled that the specification need not be enabled until the patent issues. *Id.* at 1393. The court was not faced with an undue experimentation issue in *Argoudelis* since the Applicants deposited the bacterial strain.

101. *Amgen*, 927 F.2d at 1210.

102. *Id.* at 1211. It is important to note that the court in *Amgen* did not require insertion of genetic material into a *generally available cell line*. Rather, the court only requires "a cell obtained from generally available sources." *Id.* This subtle distinction exposes the fact that the court left ambiguous what it defines as the starting material.

103. *Jackson*, 217 U.S.P.Q. at 807.

104. *Id.*

105. 858 F.2d 731 (Fed. Cir. 1988).

106. The Board of Patent Appeals and Interferences, in 1983, was the first reviewing tribunal to address whether genetically engineered organisms need to be deposited if the original strain from which the genetically engineered strain is derived is publicly available. *Ex parte Forman*, 230 U.S.P.Q. (BNA) 546, 546 (Bd. Pat. App. & Intf. 1986). Applicants' claimed a class of oral vaccines consisting of genetically engineered hybrid bacteria. The examiner rejected Applicants' claims finding that without a deposit, one of ordinary skill could not obtain the specific mutants essential to applicants' invention. *Id.* at 547. In addressing the examiner's rejection for lack of enablement under 35 U.S.C. § 112, the court reviewed the undue experimentation standard:

The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art and the breadth of the claims.

*Forman*, 230 U.S.P.Q. at 547.

The applicant attempted to distinguish *Jackson*, claiming that the undue experimentation involved in that case involved "finding additional strains over and above the deposited cultures in nature, whereas here the relevant hybrid bacterial strains are produced by genetic engineering by processes which at least begin with available bacterial strains." *Id.* at 548. The Board recognized the high level of skill in the art of molecular biology but at the same time viewed genetic engineering as producing unpredictable results, at best. The court evaluated the specification based on the above factors for undue experimentation and found the genetic engineering techniques very time consuming, the art relatively undeveloped, a lack of readily reproducible working examples and the claims broad in scope. *Id.*

The Board in *Forman* did not find a per se deposit requirement as in *Jackson*, but rather entered into an evaluation of the level of effort needed to reproduce the claimed invention. This case raised the question of whether genetic engineering had become sufficiently reproducible so that verbal descriptions of genetic manipulations on known or publicly available organisms was enabling. The Board of Patent Appeals answered: not yet. *Id.*

107. Hepatitis B surface antigen is a protein located on the surface of the hepatitis B virus. The immunoassay the applicants developed tests for the presence of the hepatitis B virus by taking a sample to be tested, adding monoclonal antibodies that selectively bind to the hepatitis B surface protein and then measuring for the antibody-antigen conjugate.

For a concise description of monoclonal antibodies and their use in immunoassays, see *Hybritech, Inc. v. Monoclonal Antibodies*, 802 F.2d 1367, 1368-71 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

108. In a separate opinion that concurred in part and dissented in part, Judge Pauline Newman discussed whether Wands had introduced sufficient evidence to justify the breadth of the claims. Wands claimed all antibodies used to assay for the hepatitis B surface protein claiming all such antibodies have the same avidity (unit of antigen-antibody binding activity). *See Wands*, 858 F.2d at 738 n.26. In light of the fact that only 4 out of the 143 antibodies tested showed high avidity, Judge Newman felt the specification did not provide sufficient reproducibility to support a claim of all antibodies possessing high avidity. *Id.* at 741-42.

109. *Wands*, 858 F.2d at 735.

110. The Board of Patent Appeals and Interferences took the position that the data presented by the applicant show that the production of high-affinity hepatitis B surface protein antibodies is unpredictable and unreliable such that it would require undue experimentation for one of ordinary skill in the art to produce the antibodies. *Id.* at 735. The PTO concluded, based on its analysis of the data presented by the patent applicant, that reproduction of the invention following the specification only yielded a 2.8% success rate making said procedure unreliable and unpredictable. *See id.* at 739 n.29.

111. *Forman*, 230 U.S.P.Q. at 740.

112. *Id.* at 737.

113. *Id.*

114. *See supra* text accompanying note 106. In *Amgen*, the court noted that it is not necessary to apply all of the undue experimentation factors outlined in *Wands* since those factors are illustrative and not mandatory. *Amgen*, 927 F.2d at 1213.

115. *Wands*, 858 F.2d at 739.

116. *See supra* note 107.

117. *See supra* text accompanying note 78.

118. *Wands*, 858 F.2d at 735.

119. *See supra* part III.A.

120. 927 F.2d 1565 (Fed. Cir. 1991).

121. *Scripps*, like *Wands*, involved the preparation of hybridoma cells that produce monoclonal antibodies of a desired activity. Antibodies are proteins that bind specifically to a region of a molecule (the antigen) much like the way a key fits a lock. Numerous different antibodies can exist for any given antigen in which the different antibodies bind to the same or different regions of the antigen molecule. In *Wands*, the court held that the specification enabled one of ordinary skill to isolate antibodies that could bind to the antigen, hepatitis B surface protein. Thus, the specification only had to enable the isolation of one of numerous possible antigen-antibody lock and key combinations. In *Scripps*, the court held that the specification enabled one of ordinary skill to find antibodies possessing the characteristics that the inventor considers constitutes the best mode embodiment. This is a significantly smaller subset of the possible lock and key combinations.

122. *Ex parte* Forman, 230 U.S.P.Q. (BNA) 546, 546 (Bd. Pat. App. & Intf. 1986).

123. *Id.* at 548.

124. *Wands*, 858 F.2d at 740.

125. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

126. *See Wands*, 858 F.2d at 741.

127. *See supra* text accompanying notes 29, 31.

128. *Id.*

129. *Id.*

130. DEPT. HEALTH & HUMAN SERVICES (OASH) PUBLICATION NO. 90-50.000 at 8-24 (Rev. Oct. 1, 1990), *quoted in* Amici Brief of American Foundation for AIDS Research et al. in Support of Petition for Writ of Certiorari, *Amgen* (No. 91-13).

131. *Amgen*, 927 F.2d at 1210.

132. *See supra* note 36.

133. *See In re* Argoudelis, 434 F.2d 1390 (C.C.P.A. 1970).

134. Amicus Brief for The American Tissue Type Culture Collection in Support of Petition for Certiorari at 3, *Amgen* (No. 91-13).

135. They deposited E. coli and yeast. These were starting materials for the production of the cells.

136. Zechariah Chafee, *Reflections on the Law of Copyright (part 1)*, 45 COLUM. L. REV. 503, 511 (1945), *quoted in* Sony Corp. of America v. Universal City Studios, 464 U.S. 417, 478 (1984).

137. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

138. Amicus Brief for The American Soc. of Microbiology at 11, *Chakrabarty* (No. 79-136) ("The absence of patenting . . . would preclude acquisition of strains by researchers and would inhibit the exchange of information that is vital to research.").

139. Amicus Brief for The Pharmaceutical Mfrs. Assn. at 13, *Chakrabarty* (No. 79-136) (quoting the PRESIDENT'S INDUSTRIAL ADVISORY SUBCOMMITTEE REPORT ON PATENT POLICY 159 (1979)).

140. Amicus Brief for The American Soc. of Microbiology at 9-10, *Chakrabarty* (No. 79-136) ("Microorganisms, however, cannot be produced easily based upon a written document and, consequently, may not be placed in the hands of other researchers by written description in a patent application. For this reason, the United States Court of Customs and Patent Appeals has mandated that a prospective patent holder for a process of making a microorganism must deposit a new microorganism in a recognized culture depository . . ."). Microorganisms, as the term is used, was intended to mean both organisms isolated from nature and genetically engineered organisms. "It should be noted that the techniques for applying genetic research will eventually become increasingly well known." *Id.* at 10 n.5.

141. PRESIDENT'S INDUSTRIAL ADVISORY SUBCOMMITTEE REPORT ON PATENT POLICY 159 (1979), *quoted in* Amicus Brief for The Pharmaceutical Mfrs. Assn. at 13, *Chakrabarty* (No. 79-136).

142. In *Argouledis*, the court held that a biological deposit is a way of satisfying the enablement requirement of § 112. 434 F.2d at 1390, 1393.

143. *See* 35 U.S.C. § 135 (1988).

144. 35 U.S.C. §§ 114, 122, 131, 132, 134 (1988).

145. *See* *Lyle/Carlstrom Assoc. v. Manhattan Store Interiors*, 635 F. Supp. 1371 (E.D.N.Y. 1986), *aff'd*, 824 F.2d 977 (Fed Cir. 1987); Note, *An Economic Analysis of Royalty Terms in Patent Licenses*, 67 MINN. L. REV. 1198, 1202, 1227 n.127 (1983); Skip Derra, *Patents Bury Biotech*, RES. & DEV., Dec., 1990, at 22.

146. 35 U.S.C. § 286 (1988).

147. This is especially true with regard to the best mode requirement. "Manifestly, the sole purpose of [the best mode requirement] is to restrain inventors from applying for patents and at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived." *In re Gay*, 309 F.2d 769, 772 (C.C.P.A. 1962). Best mode disclosure was a major issue in *Amgen*. Amgen deposited yeast and E. coli, two of the most common and readily accessible microorganisms with the ATCC in order to provide an enabling disclosure. *See supra* note 135. However, when it came to disclosing the best mode cell line, the only economically viable aspect of the invention, Amgen chose a written disclosure. This behavior may plausibly be read as an attempt to conceal the best mode.

148. *See supra* note 13.

149. *See supra* part III.

150. One of the problems the Court faced in *Amgen* that was not addressed in the opinion but was undoubtedly on the judges' minds was how to rule that a patent disclosure is insufficient to enable others to reproduce the invention when that argument is raised by a patent infringer. Genetics Institute was in an awkward position for advocating that Amgen's patent contained a non-enabling best mode disclosure. Unfortunately, only those accused of infringing a patent will ever use an non-enabling disclosure argument as a means of invalidating a patent. This means that courts are inevitably faced with parties ill equipped to argue for patent disclosure standards that ensure that the invention is described with an adequate degree of reproducibility.

151. *Northern Telecom v. Datapoint Corp.*, 908 F.2d 931, 946 (Fed. Cir. 1990) (Newman, J., concurring in part, dissenting in part), *cert. denied*, 498 U.S. 920 (1990).

152. *See supra* text accompanying note 6.

153. *Kahn v. Dynamics Corp. of Am.*, 508 F.2d 939, 942 (2d Cir.), *cert. denied*, 421 U.S. 930 (1975).

154. *Norton v. Curtiss*, 433 F.2d 779, 793-94 (C.C.P.A. 1970) ("With the seemingly ever-increasing number of applicants before it, the Patent Office has a tremendous burden. While being a fact-finding as well as an adjudicatory agency, it is necessarily limited in the time permitted to ascertain the facts necessary to adjudge the patentable merits of each application. In addition, it has no testing facilities of its own. Clearly, it must rely on applicants for many of the facts upon which its decisions are based. The highest standards of honesty and candor on the part of applicants in presenting such facts to the office are thus necessary elements in a working patent system. We would go so far as to say they are essential.").

155. *See supra* note 33 and accompanying text.

156. *See* John E. Schneider, *Microorganisms and the Patent Office: To Deposit or Not to Deposit, That is the Question*, 17 INTELL. PROP. L. REV. 73, 84 (1985); Note, *Enablement Of Biotechnological Inventions: The Deposit Requirement*, 24 SUFFOLK U.L. REV. 951, 961 (1990)[hereinafter *Enablement*].

157. *See Enablement, supra* note 156, at 961.

158. *See Enablement, supra* note 156, at 963 n.100.

159. A technology pirate can potentially take the deposited material to a country where the patentee does not have patent protection, use the biological material in the patented process and then export the finished product. This article concludes that piracy is better regulated by preventing importation rather than relaxing the disclosure requirements.

160. *See Enablement, supra* note 156, at 964-65 ("The deposit requirement facilitates infringement of biotechnological inventions. Without a deposit, the would-be infringer would have to invest time and money to obtain the basic materials necessary to practice the patented invention. The required investment would either considerably delay, or completely discourage, the infringing activity."); *Biotechnology, Partnership with Industry Essential For U.S. Biotechnology, NIH Officials Say*, DAILY REPORT FOR EXECUTIVES, Nov. 22, 1991, A-9 ("Some argue that free access to a deposit amounts to a super disclosure that gives away the invention itself in addition to the 'written recipe.' . . . This claim might be exaggerated however . . . since knowledge of how to produce and maintain cells in culture does not necessarily permit large-scale production.").

161. *See Enablement, supra* note 156, at 965 n.114.

162. Pub. Law No. 100-418, 102 Stat. 1107 (codified at 19 U.S.C. § 2901 (1988)).

163. The statute states:

Whoever without authority imports into the United States or sells or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use or sale of that product. A product which is made by a patented process will, for the purposes of this title, not be considered to be so made after-

(1) it is materially changed by a subsequent process; or

(2) it becomes a trivial and nonessential component of another product.

35 U.S.C. § 271(g) (1988).

164. John H. Barton *Patenting Life*, SCI. AM., Mar., 1991, at 40, 46.

165. *Id.*

166. *See supra* note 33 and accompanying text. This is the present cost for depositing a sample with the American Tissue Type Collection (ATTC). The ATTC is a non-profit organization and only charges to cover its costs. At present, it houses over 9000 samples from patent applications. However, this amounts to only 6% of the biological samples the ATCC stores. Annually, the ATCC distributes over 150,000 cultures to 10,000 scientists. Amicus Brief for The American Type Culture Collection in Support of Petition for Certiorari at 3, *Amgen* (No. 91-13).

167. *See supra* note 34.

168. *See* Amicus Brief for The American Type Culture Collection in Support of Petition for Certiorari at 7, *Amgen* (No. 91-13). The value of a bioculture deposit lies in the fact that scientists know precisely what they are working with. Their experiments and results are therefore *comparable* with those of other scientists who have worked on the same subject. The pioneering work of others can be verified, replicated, and built upon. A scientist and his graduate students or lab assistants do not have to waste time and resources stumbling around searching for square one—they can simply obtain a sample of it from a public depository. Researchers do not have to reinvent the wheel before trying to improve upon it. Deposits thus save taxpayers, who fund millions of dollars, because universities and foundations who receive federal funds do not have to spend months or years trying to find the starting point.

169. *Bush's 'Research Initiative' Grants Industry \$4 Billion*, BIOTECHNOLOGY NEWSWATCH, Feb. 3, 1992, at 1, 1-2.

170. The issue of when to require deposits places biotechnology companies in an awkward position. On the one hand, the companies want to be able to protect their proprietary material as trade secrets thus preventing the competition from benefiting from their efforts. On the other hand, each company would prefer free access to their competitors patented materials. This article concludes that one sure way to resolve this schizophrenic dispute is to create a bright line rule for all parties to follow. A uniform deposit requirement would accomplish this result.

171. *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988) ("One means that has been developed for complying with the enablement requirement is to deposit the living materials in cell depositories which will distribute samples to the public who wish to practice the invention after the patent issues.").

172. For a discussion of the "adequate disclosure" standard, see *supra* part III.A.

173. For a discussion of the "undue experimentation" standard, see *supra* part III.B.

174. Roger Salquist, chairman of Calgene Inc., a California biotechnology company, has been quoted as saying "while the Japanese are spending money on research, we're paying the damn lawyers. We're bleeding the system of money that could be spent on research. It's nauseating." Sandra Sugawara, *Drug Patent Race Heads to the Bench*, WASH. POST, Sep. 15, 1991, at H1.

175. Denise Gilbert, managing director of research for Smith Barney, Harris, Upham & Co., commented that patent right uncertainty makes investors wary. *Id.*

176. Don Lee, *Los Angeles Times*, June 15, 1993, at D3.

177. *See* Lawrence M. Fisher, *Still More Growth in Biotechnology?*, N.Y. TIMES, Mar. 1, 1991, at 8.

178. *Wands*, 858 F.2d at 737 (factors considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims).

179. *Id.* at 737.

180. *Bonito Boats*, 109 S. Ct. at 156.

181. *See supra* part IV.D.

182. 37 C.F.R. § 1.802(b) (1993).

183. *Id.*

184. *Wands*, 858 F.2d at 736-37 ("No deposit is necessary if biological organisms can be obtained from readily available sources or derived from readily available starting materials through routine screening that does not require undue experimentation.").

185. *See supra* text accompanying note 65.

186.. *Wands*, 731 F.2d at 741.

187. Adopting a rule requiring biological deposits to satisfy the enablement requirement would probably be too broad. As biotechnology becomes more reproducible, the issue of reproducibility will become a less significant factor for having a deposit requirement. An enablement deposit requirement could also be the source of new litigation with regard to what material needs to be deposited. For example, would the deposit of the antibodies that *Wands* isolated enable a claim covering all antibodies that bind to the hepatitis B surface protein or only those antibodies that were deposited? *See supra* text accompanying notes 29, 31.

188. Undue experimentation must be considered in light of the technology involved and the level of one of ordinary skill in the art. Thus, undue experimentation is strongly dependent on factual issues unique to each case.

189. *See supra* part IV.B.